Errata to the FDA Briefing Document
Arthritis Advisory Committee Meeting
May 9, 2012

(NDA) 203-214, Tofacitinib (CP-690,550), Pfizer Inc., for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had inadequate response to one or more disease-modifying anti-rheumatic drugs

FDA Errata to the Statistical Briefing Document

1. Table 15, page 22, the correct table should read

Table 1: ANCOVA on mTSS excluding outlying subjects (|Δ| greater than 7 units)

Treatment	N	LS Mean	Difference from PBO		
			LS Mean Difference	95% CI	P-value
Study 1044 (primary at Month 6)					
CP 5 mg	275	-0.003	-0.32	(-0.59, -0.05)	0.021
CP 10 mg	287	0.14	-0.17	(-0.44, 0.09)	0.203
PBO	138	0.32			

2. On page 21, 1st paragraph

> In contrast with the results from the full ANCOVA model, the results from this new analysis showed no statistically significant differences between either of tofacitinib doses and placebo (Table 15).

Should be revised to read (change bolded and underlined)

> In contrast with the results from the full ANCOVA model, the results from this new analysis showed no statistically significant difference **between tofacitinib 10 mg and placebo, while the difference between tofacitinib 5 mg and placebo was statistically significant** (Table 15).

3. On page 24, 2nd paragraph

> Regardless of this problem, because the test failed to reject the hypothesis that tofacitinib 10 mg is not different from placebo in mTSS when non-parametric test was applied, the gatekeeping strategy does not allow one to continue testing.

Should be revised to read

> Applying the applicant's gatekeeping strategy or some modified approaches using the pre-specified primary analysis, it is allowable to proceed to the next set of comparisons (Family 3). However, the uncertainty surrounding the results from the analyses comparing tofacitinib 10 mg and placebo in mTSS still remains.